

AMENDMENTS TO THE DRAWINGS

The attached sheet of drawings includes one sheet of formal drawings as requested by the examiner.

Attachment: Additional sheet of drawings.

REMARKS**I. General**

Claims 25-46 are pending in the present application and all are rejected in the current Office Action mailed on January 3, 2005. Claims 35-44 are amended and claims 47-50 are added by the present amendment. The outstanding issues in the current Office Action are as follows:

- The drawings are objected to under 37 C.F.R. § 1.83(a) as not showing every feature of claims 25-34.
- Claims 40-46 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out, and distinctly claim the subject matter which Applicant regards as the invention.
- Claims 25-32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 6,350,262 (hereinafter, *Ashley*).
- Claims 35-39 stand rejected under 35 U.S.C. § 102(e) as being anticipated by U.S. Patent Appl. No. 2002/0169442 (hereinafter, *Neev*).
- Claims 33-34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Ashley* in view of U.S. Patent No. 6,162,217 (hereinafter, *Kannenberg*).

Applicant respectfully requests withdrawal of the rejections in light of the amendments and remarks contained herein.

II. Amendments

Claims 35-39 are amended to recite, in part, "heat at the lesion is sustained." This amendment has not been made to distinguish the claims over the applied art, or to narrow the scope of the claim, but rather to make the wording more grammatically correct. Support can be found in the claims themselves. No new matter is added by this amendment.

Claims 35 is amended to remove "an acne" therefrom. This amendment has not been done to narrow the scope of the claim, or to distinguish the claim over the applied art.

Support can be found at paragraphs 0031-0040. No new matter is added by this amendment.

Claims 40-44 are amended to remove “average” therefrom. Applicant asserts that the amendment to these claims does not narrow the scope of the claims. No new matter is presented.

Claim 47 is added as a depending from claim 35, and presents acne as one type of skin lesion. Support can be found in pre-amendment claim 35. No new matter is added.

Claim 48-50 are added by the present amendment. Support can be found generally in the specification. No new matter is presented.

III. Drawings

On page 2 of the Office Action, the drawings are objected to under 37 C.F.R. § 1.83(a). The Examiner cited claims 25-34 as requiring drawings to the electrical device and its features. The drawings are amended to show the electrical device and its features. See the attached drawing to this amendment document showing Fig. 3. Support for the newly submitted Figure can be found in the specification at paragraphs 0046, 0050-0059, and 0066-0070. Thus, no new matter has been added. Accordingly, Applicant respectfully requests the withdrawal of the objection to the drawings under 37 C.F.R. § 1.83(a).

Further, the specification is amended to refer to Fig. 3 at paragraphs 0030a, 0046, and 0066. No new matter has been added by the amendments to the specification.

IV. Rejections Under 35 U.S.C. §112 Second Paragraph

On page 3 of the Office Action, claims 40-46 stand rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The objection of record states that it is unclear from the disclosure what an effective therapeutic amount of thermal energy is provided (watt-seconds or joules), and what published standard is used to determine the average recovery time of an acne lesion, especially since this would vary based on the lesion’s size, depth, etc. However, the Examiner provides no authority, and Applicant is not aware of any authority, for requiring

Applicant to include a specific measure of energy, such as watt-seconds or joules, and a published standard used to determine the average recovery time of an acne lesion.

The foregoing notwithstanding, Applicant has amended claim 40 to remove “average” therefrom in an effort to alleviate the Examiner’s consternation. Accordingly, claim 40, as amended, recites “delivering an effective therapeutic amount of thermal energy to the lesion that is sufficient to improve the recovery time of the acne lesion by at least 1 day.”

Applicant reminds the Examiner that functional limitations which set definite boundaries on the patent protection sought are not indefinite, see M.P.E.P. § 2173.05(g). Although not reciting a specific measure of energy in watt-seconds or joules and not referencing a published standard regarding the recovery time of an acne lesion, the claim language “delivering an effective therapeutic amount of thermal energy to the lesion that is sufficient to improve the recovery time of the acne lesion by at least 1 day” sets definite boundaries on the patent protection sought. Specifically, the recited “thermal energy” is expressly recited to be an amount that is sufficient to improve the recovery time of the acne lesion to which it is applied by at least 1 day. The recited “recovery time of the acne lesion” is expressly recited to be reduced by at least 1 day. The foregoing claim language is asserted to set definite boundaries on the patent protection sought and, thus, satisfy the requirements of 35 U.S.C. § 112, second paragraph. Accordingly, Applicant requests withdrawal of 35 U.S.C. § 112, second paragraph, rejections of claims 40-46.

V. Rejections Under 35 U.S.C. §102

On page 3 of the Office Action, claims 25-32 stand rejected under 35 U.S.C. § 102(b) as being anticipated by *Ashley*, and on page 4 of the Office Action claims 35-39 stand rejected under 35 U.S.C. § 102(e) as being anticipated by *Neev*. Applicant traverses the rejection and asserts the claims are allowable, at least, for the reasons stated below.

In order for a claim to be properly rejected under 35 U.S.C. § 102, the applied reference must teach each and every element of the claimed invention. Moreover, “[t]he identical invention must be shown in as complete detail as is contained in the ...claim.” M.P.E.P. § 2131, citing *Richardson v. Suzuki Motor Co.*, 868 F.2d 1226, 1236 (Fed. Cir. 1989). The applied art does not show the identical invention in as complete detail as in the

claim.

A. Rejections Based upon Anticipation by *Ashley*

Claim 25 recites, in part, “an interface for contacting the skin.” *Ashley* does not teach an interface for contacting the skin. The cited interface (#900 A in Figure 9 B) is the non-conductive portion of a surgical tip specifically designed to contact and protect normal tissue from the effects of the heat produced by the conductive portion of the surgical tip. (Column 11, lines 44-46). The device is designed to be used percutaneously inside a surgical site, and it is not designed for contacting the skin. (Column 2, lines 15-18). Therefore, *Ashley* does not teach an interface for contacting the skin.

Further, claim 25 recites “a temperature from a range of about 48° to about 53°C,” whereas, the Office Action cited to a range in the applied reference of “anywhere from about 60 to about 85° C.” Therefore, the temperature range of the present invention is not anticipated by the range cited in the applied reference. (Column 7, lines 2-14). Thus, *Ashley* does not show the identical invention in as complete detail as is necessary for a rejection under 35 U.S.C. § 102. Accordingly, Applicant respectfully request withdrawal of the 35 U.S.C. § 102(b) rejection of claim 25.

Claim 26 depends from, and inherits all of the limitations of, independent claim 25, shown above to be allowable. Accordingly, Applicant respectfully asserts that claim 26 is allowable for the reasons discussed above, and requests withdrawal of the 35 U.S.C. § 102(b) rejection of claim 26.

Claim 27 recites “wherein the interface is interchangeable or disposable.” The Examiner does not cite any passage in *Ashley* showing this limitation. Thus, the Applicant asserts the rejection is improper. Moreover, claim 27 depends from, and inherits all of the limitations of, independent claim 25, shown above to be allowable. Accordingly, Applicant respectfully asserts that claim 27 is allowable for the reasons discussed above, and requests withdrawal of the 35 U.S.C. § 102(b) rejection of claim 27.

Claims 28-32 all recite “...maintaining the interface at a temperature between about 48° to about 53°C...” As discussed above, *Ashley* does not teach this limitation. Moreover, claims 28-32 depend from, and inherit all of the limitations of, independent claim 25, shown

above to be allowable. Accordingly, Applicant respectfully asserts that claim 28-32 are allowable for the reasons discussed above, and requests withdrawal of the 35 U.S.C. § 102(b) rejection of claims 28-32.

B. Rejections Based upon Anticipation by *Neev*

Claim 35 recites, in part, “maintaining the thermal energy applied to the lesion at about 48°C to about 53°C for at least 30 seconds.” *Neev* does not teach this limitation. As shown by the sections cited by the Examiner, *Neev* teaches the use of photons to heat the skin that results in an “ablative or evaporative explosive removal of the top layer of the skin.” (Paragraph 0037). The system, in *Neev*, results in shorter treatment times that “should be from about 0.2 second to about 10 seconds, and preferably from about 0.5 second to about 5 seconds.” (Paragraph 0055). The short duration of less than 10 seconds of therapy does not anticipate the language of claim 35. The method of claim 35 applies thermal energy “to the lesion at about 48°C to about 53°C for at least 30 seconds.” Thus, the applied reference does not teach each and every element of the claimed invention as required for rejection under 35 U.S.C. § 102(e). Accordingly, applicant request withdrawal of the 35 U.S.C. § 102(e) rejection of claim 35.

Claims 36-39 depend directly or indirectly from, and inherit all of the limitations of claim 35. Therefore, claims 36-39 are asserted to be allowable, at least, because of their dependence from claim 35. Further, claims 36-39 recite additional new and non-obvious limitations not present in the art of record. Each claim recites a duration of time longer than 30 seconds for the application of thermal energy to the lesion. Thus, the claims are not anticipated by *Neev*. Accordingly, applicant request withdrawal of the 35 U.S.C. § 102(e) rejection of claims 36-39.

VI. Rejections Under 35 U.S.C. §103(a)

On page 4 of the Office Action, claims 33-34 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over *Ashley* in view of *Kannenberg*. Applicant traverses the rejection and asserts the claims are allowable, at least, for the reasons stated below.

“To establish a prima facie case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in

the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations.” M.P.E.P. § 2143. The art cited by the Examiner does not teach or suggest all of the claim limitations, and there is not a reasonable expectation of success for the combination.

Claims 33 and 34 recite a “heater control system” using a “feedback control mechanism involving the use of PID control algorithms” (claim 33) and “gradually ramping the temperature of the interface” (claim 34). As conceded by the examiner “*Ashley* fails to disclose the details of the controller.” The Examiner then cites to *Kannenberg* to disclose the missing details. Although not acquiescing to the Examiner’s assertions, in order for the Examiner to combine the reference teachings, there must be a reasonable expectation of success. The device in *Kannenberg* is part of a complicated “medical system used by physicians to adjust thermal energy to soft tissue.” (Column 3, line 67). It requires the physician to “set both the temperature and operating characteristics for the probes.” (Column 4, lines 13-14). Further, the described controller is a stand alone component to which the probe connects. (Column 2, lines 47-50). *Kannenberg* does not contemplate or disclose an embodiment where the controller is combined into the hand-held probe and where there is no physician interaction to adjust the parameters. (Column 2, lines 46-50). There is nothing in the art to solve the problem of making the large control system of *Kannenberg* fit in, and function with, the hand-held device of *Ashley*. Thus, there is no reasonable expectation of success with respect to the proffered combination.

Moreover, the combination of references is not proper if the “suggested combination of references would require a substantial reconstruction and redesign of the element shown in [the primary reference] as well as a change in the basic principle under which the [primary reference] construction was designed to operate.” M.P.E.P. § 2143.01 (citing to 270 F.2d at 813). The probe, in *Ashley*, is designed to be a hand-held device. The proposed combination would require substantial reconstruction and redesign to combine the stand alone control system of *Kannenberg* with the hand-held probe of *Ashley*. Proof of this point is found in *Kannenberg* itself. Even though *Kannenberg*’s control system works with a probe, it is designed placing the control system in a stand alone unit, instead of in the probe as suggested

by the Examiner. The probe must be small enough to be a hand held instrument that is easily manipulated in a surgical site. Thus, the suggested combination would require substantial reconstruction and redesign as well as a change in the basic principle of operation of *Ashley's* probe. Therefore, Applicant asserts the teachings of the references are not sufficient to render the claims *prima facie* obvious.

Additionally, claims 33 and 34 depend directly from independent claim 25, and inherit all of its limitations. As discussed above, *Ashley* does not teach all of the claim limitations of claim 25. Further, *Kannenberg* does not teach the limitations of claim 25, nor is it cited for such by the examiner. Therefore, the combined prior art references do not teach or suggest all of the limitations of claim 25. Thus, claims 33 and 34 are allowable, at least for their dependence from claim 25. Accordingly, Applicant respectfully request withdrawal of the 35 U.S.C. § 103(a) rejection of claims 33 and 34.

VII. New Claims

Claim 47 depends from claim 35, which is asserted to be allowable. Therefore, claim 47 is asserted to be allowable, at least in that it depends from claim 35.

Claim 48 recites in part “delivering an effective therapeutic amount of thermal energy to the lesion such that a surface of the lesion is maintained at a temperature of about 48° to about 53° C.” This limitation is not shown in the art. Therefore, claim 48 is asserted to be patentable over the art.

Claims 49-50 depend from, and inherit all of the limitations of, claim 48, which is asserted above to be patentable over the art. Therefore, claims 49-50 are asserted to be patentable, at least, in that they depend from claim 48.

VIII. Conclusion

In view of the above amendment, each of the presently pending claims in this application is believed to be in immediate condition for allowance. Accordingly, the Examiner is respectfully requested to pass this application to issue.

The fee for the additional claims is figured on the Transmittal sheet. At any time during the pendency of this application, please charge any fees required or credit any

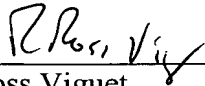
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Respectfully submitted,

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